

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/  
FENFLURAMINE/DEXFENFLURAMINE)  
PRODUCTS LIABILITY LITIGATION

MDL NO. 1203

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

v.

CIVIL ACTION NO. 99-20593

AMERICAN HOME PRODUCTS  
CORPORATION

2:16 MD 1203

**MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.**

Bartle, J.

May 8, 2013

Dianne T. Cofer ("Ms. Cofer" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust").<sup>2</sup> Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>3</sup>

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Thomas N. Cofer, Ms. Cofer's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In April, 2005, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Andrew S. Fireman, M.D. Dr. Fireman is no stranger to this litigation. According to the Trust, he has attested to at least 92 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated May 2, 2001, Dr. Fireman attested in Part II of Ms. Cofer's Green Form that she suffered from severe mitral regurgitation and had surgery to repair or replace the aortic and/or mitral valve(s) after use of Pondimin® and/or

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3. (...continued)  
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

Redux™.<sup>4</sup> Based on such findings, claimant would be entitled to Matrix A-1, Level III benefits in the amount of \$748,344.<sup>5</sup>

Dr. Fireman also attested in claimant's Green Form that Ms. Cofer did not suffer from mitral valve prolapse. Mitral valve prolapse is defined in the Settlement Agreement as:

[A] condition where (a) the echocardiogram video tape or disk includes the parasternal long axis view and (b) that echocardiographic view shows displacement of one or both mitral leaflets >2mm above the atrial-ventricular border during systole, and >5mm leaflet thickening during diastole, as determined by a Board-Certified Cardiologist.

Settlement Agreement § I.39. Under the Settlement Agreement, the presence of mitral valve prolapse requires the payment of reduced Matrix Benefits. Id. § IV.B.2.d.(2)(c)ii)b). As the Trust does not contest Ms. Cofer's entitlement to Level III benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or B-1.

In January, 2006, the Trust forwarded the claim for review by Waleed N. Irani, M.D., one of its auditing cardiologists.<sup>6</sup> In audit, Dr. Irani concluded that there was no

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4. Dr. Fireman also attested that claimant suffered from a reduced ejection fraction in the range of 50% to 60% and New York Heart Association Functional Class II symptoms. These conditions are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement § IV.B.2.c.(3)(a).

6. Pursuant to Pretrial Order ("PTO") No. 3882 (Aug. 26, 2004),  
(continued...)

reasonable medical basis for the attesting physician's finding that claimant did not have mitral valve prolapse. In support of this conclusion, Dr. Irani stated that the "[echocardiogram] dated 5/2/01 [was] of borderline quality with no obvious [mitral valve] prolapse - cardiac [catherization] dated 5/16/01 with evidence of bileaflet prolapse."

Based on Dr. Irani's finding that claimant had mitral valve prolapse, the Trust issued a post-audit determination that Ms. Cofer was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>7</sup> In contest, claimant argued that the auditing cardiologist's determination of mitral valve prolapse was improper because it was based on the report of the cardiac catheterization rather than a review of an echocardiogram as required by the Settlement Agreement. In addition, Ms. Cofer submitted a Declaration from Manoj R. Muttreja, M.D., who opined, in relevant part, as follows:

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6. (...continued)  
all Level III, Level IV, and Level V Matrix claims were subject to the Parallel Processing Procedures ("PPP"). As Wyeth did not agree that Ms. Cofer had a Matrix A-1, Level III claim, the Trust audited Ms. Cofer's claim.

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Cofer's claim.

2. I reviewed a copy of the above-referenced Claimant's left ventriculography videotape dated May 16, 2001, a copy of the transthoracic echocardiogram (TTE) videotape dated May 2, 2001, and I reviewed a copy of the Claimant's transesophageal echocardiogram (TEE) videotape dated May 16, 2001.
3. I reviewed these two echocardiogram and one left ventriculography videotapes, in detail, for the purpose of finding any evidence of mitral valve prolapse (MVP).
4. On the basis of my review of these two echocardiogram and one left ventriculography videotapes, I found no evidence of MVP.
5. In addition to my review of these three videotapes, I reviewed the cardiac catheterization report dated May 16, 2001, wherein the doctor stated that he found "Prolapse of the anterior and posterior mitral valve leaflets."
6. In my review of the TTE videotape dated May 2, 2001, I had clear parasternal long-axis views of both the anterior and posterior mitral valve leaflets as well as other views of these leaflets. MVP was clearly not present. The cardiac catheterization report, or even the left ventriculography itself, cannot be used to contradict the findings that I personally observed on the TTE.

Although not required to do so, the Trust forwarded the claim for a second review by the auditing cardiologist.

Dr. Irani submitted a declaration in which he again concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Cofer did not have mitral valve prolapse. Dr. Irani stated, in relevant part:

7. In light of Claimant's Contest, I was contacted by the Trust and asked to review Claimant's Contest Materials, as well as a copy of Claimant's transthoracic echocardiogram (TTE) videotape dated May 2, 2001, Claimant's transesophageal echocardiogram (TEE) videotape dated May 16, 2001 and Claimant's cardiac catheterization tape dated May 16, 2001.
8. In accordance with the Trust's request, I carefully reviewed the entirety of all 3 tapes (TTE, TEE and cardiac catheterization), as well as Claimant's other Contest Materials.
9. Upon careful and thorough review of the May 2, 2001 TTE, I found that there is posterior leaflet prolapse seen with an anteroseptally directed jet of mitral regurgitation. The image quality precludes exact measurement of the distance that the posterior leaflet prolapses, however, visually it appears to be 5 mm.
10. Upon careful and thorough review of the May 16, 2001 TEE, I found ... clear mitral valve prolapse.
11. Upon careful and thorough review of the May 16, 2001 cardiac catheterization I found that mitral valve prolapse is present.
12. I also re-reviewed and considered the cardiac catheterization report accompanying the May 16, 2001 cardiac catheterization tape, wherein the doctor confirmed that there was "Prolapse of the anterior and posterior mitral valve leaflets."
13. Based on my review of the 3 tapes (TTE, TEE and cardiac catheterization), the cardiac catheterization report and Claimant's other Contest Materials, I affirm my findings at audit, that there is no reasonable medical basis for a finding that the Claimant does not have

mitral valve prolapse as defined in the Settlement Agreement.

The Trust then issued a final post-audit determination, again determining that Ms. Cofer was entitled only to Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Cofer's claim should be paid. On November 20, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6696 (Nov. 20, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on February 5, 2007, and claimant submitted a sur-reply on February 27, 2007. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor<sup>8</sup> to review claims after the Trust and claimant have had the opportunity to develop the Show Cause

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8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she did not have mitral valve prolapse as defined in the Settlement Agreement. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Cofer reasserts the arguments made in contest. Claimant also argues that she has established a reasonable medical basis for the attesting physician's finding that she did not have mitral valve prolapse as defined in the Settlement Agreement because "the Trust has offered no evidence in support of its claim that it met the definition of [mitral valve prolapse] that is found in the



Settlement Agreement."<sup>9</sup> She also contends Dr. Irani did not use the criteria set forth in the Settlement Agreement.

Specifically, claimant asserts the auditing cardiologist failed to state whether he determined the presence of mitral valve prolapse in the parasternal long axis view and that the mitral valve prolapse found to be present exceeded 2 mm in systole and 5 mm in diastole, as required by the Settlement Agreement.

Further, claimant contends that Dr. Irani is not qualified to diagnose mitral valve prolapse because his curriculum vitae does not evidence that he is an invasive cardiologist or that he is Board-Certified.

In response, the Trust argues that the auditing cardiologist is Board-Certified and complied with the terms of the Settlement Agreement because he found mitral valve prolapse of 5 mm on claimant's May 2, 2001 echocardiogram and observed mitral valve prolapse on claimant's May 16, 2001 echocardiogram and cardiac catheterization. The Trust also argues that claimant's medical records support the finding of mitral valve prolapse as her June 11, 2001 operative report notes "a long history of mitral valve prolapse." Finally, the Trust argues that Dr. Muttreja's Declaration does not provide a reasonable medical basis for Dr. Fireman's Green Form representation because

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9. Claimant also asserts that the issue of reasonable medical basis should be controlled by Gallagher v. Latrobe Brewing Co., 31 F.R.D. 36 (W.D. Pa. 1962). We repeatedly have rejected the Gallagher decision as controlling or persuasive. See, e.g., PTO No. 6275 (May 19, 2006).

he does not deny the existence of mitral valve prolapse on claimant's cardiac catheterization.

The Technical Advisor, Dr. Vigilante reviewed claimant's echocardiograms and concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Coffey did not have mitral valve prolapse.

Specifically, Dr. Vigilante stated, in relevant part, that:

I reviewed the Claimant's echocardiogram of attestation dated May 2, 2001.

....

I digitized the cardiac cycles in the parasternal long-axis view and made measurements with electronic calipers. There was displacement of the posterior leaflet 4 mm above the atrial-ventricular border during systole. The posterior mitral leaflet measured 7 mm in thickness during diastole. Additionally, prolapse of the posterior mitral leaflet was noted in the apical two chamber view. Findings on this echocardiogram correlate with the findings noted at the time of surgery by Dr. Ewing. At that time, he stated, "The valve did indeed show changes of myxoid degeneration. There was some prolapse of the anterior leaflet, but this did not appear to be severe. The primary area of leak appeared to be at the posterior or non-aortic commissure where there was some prolapse and the leaflets did not coapt."

....

I reviewed the Claimant's transesophageal echocardiogram of May 16, 2001.... There was clear evidence of prolapse of the posterior mitral left leaflet at the 139 degree to 180 degree views. This prolapse primarily occurred in the P1 segment of the posterior mitral leaflet....

I reviewed the Claimant's cardiac catheterization of May 16, 2001.... After the first two premature ventricular beats, it was clear that significant prolapse occurred with "billowing" of the mitral valve into the left atrium during systole consistent with significant mitral valve prolapse....

... [T]here is no reasonable medical basis for the Attesting Physician's answer to Green Form Question D.7. That is, I was able to determine that the echocardiogram of attestation demonstrated mitral valve prolapse as defined in the Green Form. This finding was also supported by the findings on the transesophageal echocardiogram, cardiac catheterization and by the findings at the time of the cardiac surgery. An echocardiographer could not reasonably conclude that mitral valve prolapse was not present on this study even taking into account inter-reader variability.

After reviewing the entire Show Cause Record, we find the claimant's arguments are without merit. The Settlement Agreement requires that a claim for damage to the mitral valve be reduced to Matrix B-1 if he or she has mitral valve prolapse. Settlement Agreement § IV.B.2.d.(2)(c)ii)b). As noted above, mitral valve prolapse is defined as:

[A] condition where (a) the echocardiogram video tape or disk includes the parasternal long axis view and (b) that echocardiographic view shows displacement of one or both mitral leaflets >2mm above the atrial-ventricular border during systole, and >5mm leaflet thickening during diastole, as determined by a Board-Certified Cardiologist.

Id. § I.39.

Claimant has not satisfied her burden of establishing that there was a reasonable medical basis for Dr. Fireman's finding that she did not have mitral valve prolapse. Although

Ms. Cofer contests the findings of the auditing cardiologist because he relied on a cardiac catheterization rather than an echocardiogram, Dr. Irani subsequently re-reviewed Ms. Cofer's submissions and determined that claimant's echocardiograms of May 2, 2001 and May 16, 2001 and her cardiac catheterization of May 16, 2001 all demonstrated mitral valve prolapse. Thus, we reject claimant's argument that Dr. Irani relied solely on claimant's cardiac catheterization as the basis for his finding.

We also disagree with Ms. Cofer that the Declaration of Dr. Muttreja provides a reasonable medical basis for Dr. Fireman's representation that claimant did not have mitral valve prolapse. Although Dr. Muttreja states, in conclusory fashion without any measurements or specific detail regarding claimant's echocardiograms or catheterization, that Ms. Cofer did not have mitral valve prolapse, the Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiograms and cardiac catheterization and concluded that they demonstrated mitral valve prolapse as defined by the Settlement Agreement.<sup>10</sup> Specifically, with respect to Ms. Cofer's May 2, 2001 echocardiogram, Dr. Vigilante observed that, in the parasternal long-axis view, "there was displacement of the posterior leaflet 4 mm above the atrial-ventricular border during systole" and that the "posterior mitral leaflet measured 7 mm in thickness during diastole."

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10. Despite the opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

These measurements satisfy the definition of mitral valve prolapse set forth in the Settlement Agreement. As claimant does not identify any specific errors by Dr. Vigilante, she cannot meet her burden of proof.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she did not have mitral valve prolapse as defined in the Settlement Agreement. Therefore, we will affirm the Trust's denial of Ms. Cofer's claim for Matrix A benefits and the related derivative claim submitted by her spouse.